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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,315

02/23/2005

Lisa Selsam Beavers

X-15968

5363

25885

7590

04/11/2008

ELI LILLY & COMPANY

PATENT DIVISION

P.O. BOX 6288

INDIANAPOLIS, IN 46206-6288

EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

04/11/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,315	<b>Applicant(s)</b> BEAVERS ET AL.	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-5, 7 and 8 are pending.

Claims 6, 12-15 have been cancelled.

The objection on claim 15 has been withdrawn as applicants have cancelled the claim.

The rejection of claim 2 and 3 under 35 USC 112 second para has been withdrawn as applicants have amended the claims. The rejection over claim 7 has also been withdrawn as applicants have amended the claim.


The rejection of claims 1-8, 12-15 has been partially withdrawn.


It is withdrawn with respect to 1), 3) and 5).

But it still stands for 2 and 4.

Applicants arguments are not found to be convincing that the data for just 2 compounds are sufficient to cover the activity for the full scope of the claimed invention.

First of all the data provided for the 2 compounds is quite different. Second the scope of the compound is very broad. Compound 6 is drawn to G1 is a CH<sub>2</sub>-CH<sub>2</sub> and X being a COR<sub>3</sub>

wherein R<sub>3</sub> is a  and compound 60 is drawn to G1 being a CH<sub>2</sub> and X is CH<sub>2</sub> R<sub>4</sub>

wherein R<sub>4</sub> is a . even though both are heteroring the data is quite different.

In the article of Ether derivatives of 3- piperidino- propan-1-ol..., Dorota Lazewska et al, 2006 compound 2 has the most agonistic activity see the conclusion.

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#### 4. Conclusion

In this study, we report on novel potent histamine H<sub>4</sub> receptor ligands. These compounds are ether derivatives of 3-piperidinopropyl-1-ol. They proved to be histamine H<sub>4</sub> receptor ligands investigated in [<sup>3</sup>H]histapropylate binding studies on the human histamine H<sub>4</sub> receptor and showed affinities from high to low nanomolar concentration range. In vivo screening of selected compounds showed the highest antagonist potency for the ethyl ether derivative 2.

Other derivatives 17-19 are highly potent both in vitro and in vivo studies and may be interesting subjects for further investigation and development.

This is from 19 compounds that were made.

Thus the state of the art is highly unpredictable.

Applicants compounds have several substituent and can change the properties and activities.

Thus the properties are unpredictable. . With so many R3, R4 , R5 variables, the activity is not predictable.

Applicants have made some compositions but until they are enabled for a “pharmaceutical” use ( i.e. treating a disease) they are not enabled under 35 USC 112.

Hence the rejection still stands.

The rejection under 35 USC 102 (b) over JP50106977, JP50142576, JP5300534, and JP57080322. has also been withdrawn as applicants have amended the claims.

The rejection of the claims under 35 USC 102(c) has also been withdrawn as applicants have cancelled the compound in claim 7 and has also amended the claims.

The claims 1-8, 12-15 rejected under 102 (a) as being anticipated by WO 2002014237 has also been withdrawn as applicants have put in a proviso.

New rejection :-

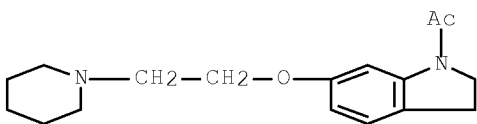
### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2002014273 Bromidge et al.

The reference discloses compound wherein G1 is CH<sub>2</sub>, and X is a COR<sub>3</sub>, i.e. COCH<sub>3</sub>. wherein R<sub>3</sub> is an alkyl.



( Applicants should take care while amending the claims so as not to introduce new matter.)

### ***Claim Rejections - 35 USC § 103***

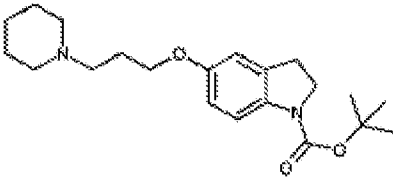
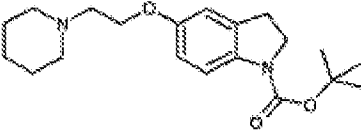
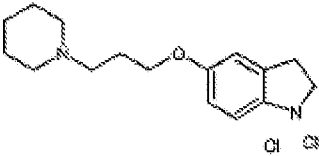
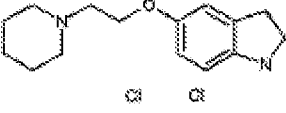
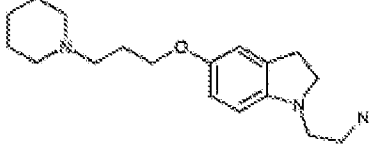
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2002014273 Bromidge et al.

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Applicants claims are drawn to a genus that encompasses compounds such as.

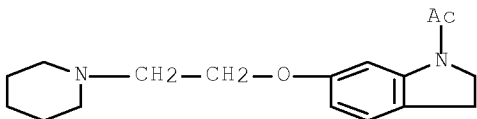
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*Scope & Content of Prior Art MPEP 2141.01*

The prior art teaches compounds

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The WO Bromidge document teaches the compounds such as



and also with NH group which applicants have provisoed out.

*Difference between Prior Art and the claims MPEP 2141.02*

The difference is in the X group.

The prior art teaches the H and the acetal.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

The prior art teaches the H and alkyl verses the H is prima facie obvious . In re Wood.

Also applicants claim the salts and even though they have provisoed out the compound the hydrochloride salt would also be a prima facie obvious modification.

Thus to one skilled in the art it would be obvious to modify the compounds to obtain the compounds of this invention, which are the salts and the also with X being an alkyl group.

***Conclusion***

Claims 1-5, 7 and 8 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
April 4th , 2008.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625